APR - 2 1997

510(k) Summary
SpaceLabs Medical Integrated Multi-Parameter Module
K952912

1. Submitter's Name

SpaceLabs Medical Inc.
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2. Name of Device: SpaceLabs Medical Integrated Multi-Parameter Module

Classification: SpaceLabs Medical Integrated Multi-Parameter Module is classified under Arrhythmia Detector and Alarm (No. 74DSI) which has been classified as a Class III device, in accordance to 21 CFR 870.1025.

SpaceLabs Medical Integrated Multi-Parameter Module is also classified under Noninvasive Blood Pressure Measurement System (No. 74DXN) which has been classified as a Class II device, in accordance to 21 CFR 870.1130.

SpaceLabs Medical Integrated Multi-Parameter Module is also classified under Oximeter (No. 74DQA) which has been classified as a Class II device, in accordance to 21 CFR 870.2700.

3. Predicate Devices:

a. SpaceLabs Medical 90352 PC Scout Expansion Housing, as described in K945429.
b. SpaceLabs Medical 90492 ECG Module, as described in K942058;
c. SpaceLabs Medical 90478 Telemetry Receiver, as described in K922510;
d. SpaceLabs Medical 90553 NIBP Monitor, as described in K941167;
e. Nellcor N-180 pulse oximeter, as described in K913695;
f. SpaceLabs Medical 90489 SpO2 Module, as described in K901209;
g. Hewlett Packard CMS and M1175A, as described in K882609 and K900032; and
h. Marquette Tramscope System, as described in K900598.

4. The SpaceLabs Medical Integrated Multi-Parameter Module is designed to acquire, process, and display electro-cardiogram vectors (ECG), respiratory effort, non-invasive blood pressure (NIBP), and pulse oximetric oxygen saturation (SpO2) using standard ECG electrodes, NIBP cuffs, and SpO2 sensors and be exclusively used with the SpaceLabs Medical Integrated Multi-Parameter Module along with the PCMS Monitor. Operation, set-up, and alarm limit settings are all controlled by simple menu choices via the PCMS Monitor.

5. The SpaceLabs Medical Integrated Multi-Parameter Module is designed to acquire, process and display up to two ECG vectors and the respiratory effort signal using standard ECG electrodes plus one channel of noninvasive blood pressure and one channel of pulse oximetry.

   The SpaceLabs Medical Integrated Multi-Parameter Module is intended for use as a ECG monitor and an arrhythmia detector, which monitors the electrocardiogram and is designed to produce a visible and audible signal (via a SpaceLabs Medical PCMS monitor) when an arrhythmia, such as premature ventricular contraction, ventricular fibrillation, asystole, high/low heart rates, ventricular runs, or tachycardia, exists. In addition, ST segment deviations are detected.

   The SpaceLabs Medical Integrated Multi-Parameter Module is also intended for use as a non-invasive blood pressure system, a pulse oximeter, and a monitor of respiratory effort.

   The SpaceLabs Medical Integrated Multi-Parameter Module is intended for use on both adult and neonatal patient populations in all clinical settings. The SpaceLabs Medical Integrated Multi-Parameter Module is not intended for home use. The intended uses of this device are substantially equivalent to its predicate devices.

6. The SpaceLabs Medical Integrated Multi-Parameter Module provides multiple lead ECG monitoring from electrodes placed on the body surface. Electrical activity of the heart is measured via multiple electrodes placed at various locations on the patient's body.

   Non-invasive blood pressure measurements are acquired through a conventional inflatable cuff mechanism that is considered to be standard of care. The SpO2 channel is designed to noninvasively and continuously monitor functional oxygen saturation by the standard photoelectric pulse oximetric technique.

   The design, material used, and energy source are similar to its predicate devices.